K002908

AUG 3 0 2001

# 510(k) SUMMARY
# Jet Therapy Therapeutic Massager

September 15, 2000

This summary is provided in accordance with the Safe Medical Devices Act of 1990 (SMDA). The information provided in the 510(k), PreMarket Notification, was in accordance with 21 CFR 807.87.

1. **Submitter of 510(k):**


| | |
|---|---|
| Company Name: | Jet Therapy<br>205 Northway, Durban North<br>KawZulu-Natal<br>South Africa 4051 |
| Contact Person | Owen B. Lamb, Ph.D. Qualitivity<br>12948 N. Eagle Mesa Pl. Marana, AZ 85653 |
| Telephone: | 1 (520) 572-8414 |
| Fax | 1 (520) 572-8415 |
| e-mail | oblamb@ worldnet.att.net |


2. **Name of Device**

Trade/Proprietary Name: Jet Therapy

Common/Usual Name: Therapeutic Massage Device

Classification Name: 21 CFR 890-5660 Therapeutic Massage, Class II

**3. Legally Marketed Predicate Devices**

The Jet Therapy Therapeutic Massager is substantially equivalent to many legally marketed therapeutic massagers, including those listed in Table 1 on the next page.

**4. Device Description**

The Jet Therapy therapeutic massager is a massage device covered by 21 CFR 890-5660. It is electrically powered and uses compressed air delivered through specifically shaped hand pieces to cause mobilization of the tissue in much the same manner as a physical therapist using hands would massage the surface of the body to temporarily improve local blood circulation for the relief of minor muscle aches and pain.

# COMPARISON OF TECHNOLOGICAL CHARACTERISTICS OF THE PREDICATE DEVICES AND THE JET THERAPY THERAPEUTIC MASSAGER

| Manufacturer | Device Name | 510(k) number | Technical characteristics | Power source |
|---|---|---|---|---|
| Jet Therapy<br>205 Northway, Durban North<br>KwaZulu-Natal<br>South Africa 4051 | Jet Therapy | not yet assigned | Electrically driven air compressor, provides treatment media (compressed air) which simulates the hand massage by physical therapist otherwise known as mobilization of tissue. This effect provides relief from minor muscle pain and spasm and temporarily improves local blood circulation. | 240/120 vac air compressor isolated from rest of system by plastic pipe and Tygone™ tubing Ground current leakage is not an issue with this device based on this feature. |
| LPG USA<br>3101 North Federal Highway, Suite 301<br>Fort Lauderdale, FL 33306 | LPG Massager/Vibrator | K990445 | This device involves mobilization of tissue using the skin fold rolling technique which is achieved using vacuum to lift the skin fold and motorized rollers which provide for cyclic pulsation and mobilization which replicates the hand technique of the physical therapist. This technique provides relief from temporary minor muscle pain and spasm, and temporarily improves local blood circulation. | 240/120 vac, 60 cycles powering a vacuum pump and the mechanical rollers which power this device |
| Physio Technology, Inc.<br>1925 West 6th Street<br>Topeka, KS 66606 | G5 Apparatus T, K1, K3, & The Presidents Model | K850851 | The device has 17 applicators, 3 models and is hand held. The device is a vibrator and makes claims for relief of minor muscle pain. | This 0.25 HP, 110 vac, 60 cycle device weight 3.8 pounds. The device is 12"X3"X3" . It has a ground current leakage of <75 miniamps. |
| Conair Corp.<br>1 Cummings Point Road<br>Stamford, CT 06904 | Vibratouch II Cordless Wand Massager | K912383 | This battery-powered vibrator makes claims for the relief of minor muscle pain. | Battery powered. |

Based on the information above, "Jet Therapy therapeutic massager" is substantially equivalent to the above listed devices and most other "therapeutic massagers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2001

Jet Therapy
c/o Owen Lamb, Ph.D.
Qualitivity
12948 North Eagle Mesa Place
Marana, AZ 85653

Re: K002908
Trade/Device Name: Jet Therapy
Regulation Number: 21 CFR 890.5660
Regulatory Class: Class I
Product Code: ISA
Dated: May 31, 2001
Received: June 6, 2001

Dear Dr. Lamb:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K002908

Device Name: JET THERAPY

Indications for Use: "For temporary relief of minor muscle pain and to temporarily increase localized skin blood flow"

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

for Mark N Milhouse

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K002908